AUG 0 7 2002

K021492

TAB H
XIII. 510(k) Summary

Pursuant to the Food and Drug and Cosmetic Act § 513(1)(B)(3)(A) as amended by the Safe Medical Device Act of 1990, this sponsor is providing a 510(k) Summary for the proposed device.

510(k) SUMMARY

Submitter Personal Products Company Division of McNeil-PPC Inc.
199 Grandview Road
Skillman, New Jersey 08558-9418

Contact Person Marylou Panico
Mgr. Regulatory Affairs
(908) 904-3709 phone
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Date Prepared May 3, 2002

Proprietary Name K-Y® Brand
WARMING LIQUID Personal Lubricant

Common Name Personal Lubricant

Classification Name Condom 21CFR § 884.5300 Product Code 85HIS

Predicate Device K-Y® Brand LIQUID Personal Lubricant

Description of Device
K-Y® Brand WARMING LIQUID is a non-sterile clear non-staining, non-greasy, high viscosity liquid gel used as a personal lubricant. This product is highly lubricous and may be used with or without a latex condom during intimate sexual activity. K-Y® Brand WARMING LIQUID is not a contraceptive or spermicide. It is compatible with latex condoms as demonstrated in Condom Compatibility Testing conducted according the standards defined by ASTM D 3492.

Intended Use
Patient lubricants are devices intended to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device. When used as an accessory to a medical device such as a condom, they are considered Class II Medical Devices.

K-Y® Brand WARMING LIQUID is principally intended as personal lubricant to supplement the body's own natural lubricating fluids, to moisturize, relieve friction and to enhance the ease and comfort of intimate sexual activity. This lubricant may be safely applied to vaginal, anal or penile tissue for purpose of lubrication, and moisturization. It is also compatible with latex condoms.

Technological Characteristics
K-Y® Brand WARMING LIQUID formula is proprietary. The product is however has no exceptional technological characteristics consisting mainly of water soluble ingredients similar to other lubricants currently on the market.

Substantial Equivalence

This product has been shown in laboratory testing to be substantially equivalent to the currently marketed K-Y® Brand LIQUID Personal Lubricant. Both devices have the same intended use and similar formulas slightly varied ingredients. The unique feature of the K-Y® Brand WARMING LIQUID product is that this formula provides a warming sensation upon application. Comparable lubricity of the proposed K-Y® Brand WARMING LIQUID and the marketed K-Y® Liquid products was demonstrated in laboratory coefficient of friction testing.

Preclinical Testing of Formulation

Preclinical biocompatibility studies on K-Y® Brand WARMING LIQUID was conducted by outside laboratories, in compliance with Good Laboratory Practices (GLPs) demonstrated:

- in a Dermal Sensitization Study that the product was considered not to be a contact sensitizing agent in albino guinea pigs.
- in a Rabbit Penile Irritation Study that the product did not cause any significant adverse effects when directly administered to the rabbit penis and based on macroscopic and microscopic findings did not produce any significant irritation.
- in a 10-Day Rabbit Vaginal Irritation Study, that the product did not cause any pharmacotoxic effects when administered vaginally to rabbits for 10 consecutive days. K-Y® Brand WARMING LIQUID was minimally irritating to the rabbit vaginal epithelium but considered acceptable for use in humans.
- in a Mouse Systemic Injection Study that a 25% w/v the product did not cause mortality and was not associated with systemic toxicity when administered at 50mg/kg using the i.p. route of administration.

Clinical Testing

In a Human 21-Day Cumulative Irritation Assay, this product under occluded conditions was considered to be only mildly irritating and elicited no evidence of sensitization on the skin of healthy humans.

In a Human Repeat Insult Patch Test (Modified Draize Procedure), this product was compared to the currently marketed K-Y® Liquid for its potential for contact sensitization. This study concluded that K-Y® Brand WARMING LIQUID was considered essentially non-irritating and did not elicit evidence of sensitization on healthy human skin.

A Two-Phase Consumer Use Study provided data on consumer (Males and Females) perception of warmth with a single application of the K-Y® Brand WARMING LIQUID product at the test facility, as well as actual use at home during sexual activity. Female subjects received gynecological examinations at baseline and following the last intercourse episode. The study was conducted in compliance with 21CFR 812 for Investigational Device Exemption. This study concluded that, greater than 85% of the participants perceived a warming sensation while using the product. Additionally, after one week of home use, (with a minimal of two sexual intercourse encounters) there was no observed irritation upon gynecological examination.

Preclinical and Clinical testing conducted on this formulation has demonstrated scientific evidence that this product is safe for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Ms. Marylou Panico
Manager, Regulatory Affairs
Personal Products Company
Division of McNeil-PPC, Inc.
199 Grandview Road
SKILLMAN NJ 08558

FEB 24 2014

Re: K021492
Trade/Device Name: K-Y® Brand WARMING LIQUID™ Personal Lubricant
Regulation Number: 21 CFR §884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated (Date on orig SE ltr): May 8, 2002
Received (Date on orig SE ltr): May 9, 2002

Dear Ms. Panico:

This letter corrects our substantially equivalent letter of August 7, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) INDICATIONS FOR USE FORM
(Replica of FDA Form)

510(k) Number (if known): K021492

Device Name: K-Y® Brand
WARMING LIQUID™ Personal Lubricant

Indications For Use:
Personal Lubricant (compatible with latex condoms)

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-the-Counter-Use ✓
(per 21 CFR 801.109)

David G. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021492